REMARKS

Claims 1-8, 10-17, 21-32 and newly entered claims 33-37 are pending and allegedly rejected. Applicant currently requests cancellation of Claim 37. Applicant respectfully points out that Claims 9, 18-20 were subject to cancellation during a previous restriction requirement.

Claims are currently amended, notwithstanding Applicant's belief that cancelled and unamended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicant's business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).[1]

Finally, the Examiner states "Applicant's submission filed on May 22, 2007, has been entered." (Office Action mailed 8/7/2007, page 2) and then states "[t]he Office did not receive any Declaration in the papers received on May 22, 2007." (Office Action mailed 8/7/2007, page 9). While the Examiner perhaps missed it because it was not entered as a separate file and was added to the back of the argument file, Applicant respectfully points out that the Image File Wrapper on the U.S. Patent and Trademark Office's website contains a complete image of a received Declaration, under 37 CFR 1.132, with a PTO stamp-in date of 5/22/2007 (Appendix A).

I. Specification: Title.

The Examiner continues to object to a Title suggested by the Applicant for "not being descriptive of the elected invention." Thus the Applicant's amend the Title according to the Examiner's suggested Title, "LUT1 gene from Arabidopsis and its use in engineering carotenoid metabolism in plants - -." (Office Action mailed March 21, 2006, page 4). However the Applicant continues to respectfully disagree that the suggested Title accurately describes the invention and would like to respectfully state on record that the Title suggested by the Applicant's amendments in the Request for Continued

---

[1] 65 Fed. Reg. 54603 (September 8, 2000).

Examination (mailed May 18, 2007) "Novel Carotenoid ε- and β-Hydroxylases for use in engineering carotenoid metabolism in plants." is descriptive of the elected inventions.

II. Claim Objections.

In the Office Action mailed August 7, 2007 (pages 2 and 3), the Examiner states objections to informalities in Claims 22 and 33. In response, the Applicant's amended Claims 22 and 33, please see above, according to the amendments suggested by the Examiner.

III. Indefiniteness Rejections.

In the Office Action mailed August 7, 2007, the Examiner states that "Claims 33, 35 - 37 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the Applicant regards as the invention." (Office Action mailed August 7, 2007, page 3). In particular regards to Claim 33, the Examiner requests the Applicant "[t]o amend the claim to remove the parentheses and to clearly indicate what compounds are encompassed by the claim." (Office Action mailed August 7, 2007, page 4). In response, the Applicant amended Claim 33 as suggested. Further, in response to the Examiner's suggestions (Office Action mailed August 7, 2007, page 4), Applicant amended Claim 35 to provide clear antecedent to the claim terms in Claim 36. The Applicant cancels Claim 37.

IV. Written Description Rejections.

In the Office Action mailed August 7, 2007, the Examiner states that Claims 1-8, 11-17 and 21-37 are allegedly rejected by the Examiner "as failing to comply with the written description requirement." (See, last paragraph, page 4). Further, the Examiner states that the claims contain subject matter which was not described in the specification in such a way as to convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the invention." (Office Action mailed August 7, 2007, pages 4-5). The Applicant respectfully disagrees.

Further, the Examiner supports this rejection by citing case law, in particular, "*University of California v. Eli Lilly, and Co.*, 119F. 3d 1559; 43 USPQ2d 1398, 1406

(Fed. Cir. 1997)." Applicant briefly addresses the Examiner's statements concerning written description and the Examiner's reliance on *Regents of the University of California v. Eli Lilly*. It must be stressed that the law has evolved considerably since the *Eli Lilly* case. The Examiner is asked to take note of more recent Federal Circuit decisions, such as *Capon v. Eshhar v. Dudas*, 418 F.3d 1349 (Fed. Cir. 2005) and *Falkner v. Inglis*, 79 USPQ2d 1001 (Fed. Cir. 2006). In the *Capon* case, the specification (let alone the claim) did not contain a single sequence. Similarly, in the *Falkner* case, the specification provided no sequences. The Federal Circuit found that the claims were nonetheless adequately supported in both cases. The Federal Circuit's decision in the *Falkner* case was unanimous and contained the following warning:

> "Specifically, we hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure."

It is respectfully submitted that the present case is in an even better posture than the *Capon* or *Falkner* case. In the present case, the specification DOES provide sequences, at least 45 sequences are shown in Figures 18-32. Furthermore, the Examiner is asked to take note of the following description and Figures 9, 18-31. The specification contains a description of examples for making a transgenic plant comprising SEQ ID NO:04, in fact, at least eight transformants were evaluated (see, EXAMPLE 3, Mutant Complementation, Characterization, and the Identification of LUT1 paragraph [0335] where "The identity of At3g53130 as LUT1 was initially demonstrated by molecular complementation analysis. Homozygous lut1-1 mutants were transformed with a 4.2 kb genomic DNA fragment from wild type Columbia (the background of lut1) containing the At3g53130 coding region, 1.0 kb upstream of the start codon, and 0.7 kb downstream of the stop codon. Eight independent transformants were selected and all showed a wild type lutein level when analyzed by HPLC (FIG. 3D)." Additionally, the specification contains numerous examples of LUT1 genes and polypeptides of other plants, see, EXAMPLE 6, CYP97 Homologs in Other Species paragraph [0342].

In furtherance of Applicant's assertion that the written description is adequate, the Applicant directs the Examiner's attention to another opportunity to evaluate the attached

Declaration of Dr. Dean DellaPenna that demonstrates that a person of ordinary skill in the art[2] other that the inventor was able to make and identify a nucleic acid sequence encoding a polypeptide at least 78% identical to SEQ ID NO:4[3].

Specifically, Dr. DellaPenna states:

> The specification provides the structure for SEQ ID NO:4 and homologs such as rice CYP97C (LUT1; SEQ ID NO:16). The person of skill in the art would be able to make or identify nucleic acid sequences encoding proteins that are at least 72% identical to SEQ ID NO:4 (Figure 9). Many methods for making sequences with the requisite identity are taught in the specification, for example, at pages 51-64. The specification further teaches methods for screening for functional LUT1 sequences by complementation of LUT1 mutants in Examples 3 and 5. This structural information and the screening procedures allows the person of skill in the art to identify a genus of nucleic acid sequences encoding proteins at least 72% identical to SEQ ID NO:4 that have functional LUT1 activity as claimed.

Moreover, Dr. DellaPenna describes a publication[4] wherein an Arabidopsis CYP97C (LUT1) sequence was used to identify a CYP97C homolog in Oryza sativa (rice). Moreover, at the time of filing of the present inventions, the Applicant's had already used an Arabidopsis CYP97C (LUT1) to identify the rice homolog of SEQ ID NO:4, shown as SEQ ID NO:16 in Figure 23, with 78% homology to SEQ ID NO:4, *See*, Figure 9 of the instant application. Further demonstrating that rice CYP97C (LUT1) nucleotides were indeed identified at the time of filing the present application.

Furthermore, the Applicant used structural features of SEQ ID NO:4, specifically including p450 activity related sequences and targeting sequences, to identify a large genus of p450 molecules homologous to SEQ ID NO:4 (LUT1), including CYP97C sequences at least 72% homologous (see, wheat SEQ ID NO:18 in Figures 23 and 9), CYP97A sequences, and CYP97B sequences, where examples of such molecules were provided in the specification, for example, "The Arabidopsis genome also contains two other CYP97 family members, CYP97A3 and CYP97B3, which are 49% and 42%

---

2 See, "Declaration Pursuant To 37 C.F.R. 1.132," paragraph 2.

3 Id, at paragraphs 2 and 3.

4 Quinlan *et al.*, *Escherichia coli* as a platform for functional expression of plant P450 carotene hydroxylases, Archives of Biochemistry and Biophysics 458 (2007) 146–157.

identical to the LUT1 protein, respectively. . . Additional CYP97 family proteins were identified in the EST and genomic databases from a wide variety of monocots and dicots, including Arabidopsis, barley, rice, soybean, and pea (FIG. 5)." [CYP97 Homologs in Other Species paragraph [0342] in the published specification]. The Applicant further points to Figure 10 of the present inventions showing one example of specific internal structural features of the disclosed Arabidopsis LUT1 SEQ ID NO:04 that was used to identify a large genus of molecules, including CYP97A, CYP97B, and CYP97C. Therefore the application indeed teaches a LUT1 SEQ ID NO:4 in addition to a larger genus of molecules, specifically CYP97A, CYP97B and CYP97C p450 families, which demonstrated that structural information derived from SEQ ID NOs:04 and 05 was plainly understood and used by a person of ordinary skill in the art at the time of filing of the present inventions.

Therefore, it is clear that as of the filing date of the instant invention, a person of ordinary skill in the art could make and identify nucleic acid sequences encoding a polypeptide at least 72% identical to SEQ ID NO:4 whose structural information can be and was used to identify a large genus of molecules having monooxygenase P450 activity, CYP97A, CYP97B and CYP97C families. Furthermore, that person could and did use such sequences to make vectors and transgenic organisms as described in the specification.

Thus the written description requirements were met. Accordingly, the Applicant respectfully requests the withdrawal of these rejections.

V. Enablement Rejections

Claims 1-8, 10-15, 21-37, were rejected under 35 U.S.C. §112, first paragraph, pages 5-6, as allegedly failing to comply with the enablement requirement, the Examiner continues to refer to statements/arguments the Examiner made in the Office Action mailed March 21, 2006. In particular, the Examiner states, " . . . one of skill in the art would not know how to use the nucleic acids and vectors for prokaryotic or yeast expression (claims 11 and 14 are specifically not enabled for these reasons)." (Office Action mailed March 21, 2006, pages 7-11). Further, in the Office Action mailed December 18, 2007, the Examiner invited the Applicant to "submit evidence in the form

of data/declaration under 37 C.F.R. 1.132 showing that a nucleic acid encoding SEQ ID NO:04 can be successfully expressed in yeast or *E. coli* . . .. " The Applicant responded by submitting a declaration signed by the inventor[5] who is "one of skill in the art" demonstrating expression of a rice homolog of LUT1 in *E. coli*[6]. The Applicant provides another opportunity for the Examiner to evaluate the amended claims in light of the submitted Declaration (see Appendix A). Furthermore, within the Declaration the inventor pointed out that in a recent publication, Quinlan *et al.*, *E. coli* expressing a rice CYP97C (LUT1) homolog showed an increase in production of molecules with ε-ring hydroxylation in contrast to *E. coli* not expressing the rice CYP97C sequence. Thus the Applicant respectfully asserts that the enablement requirement was met.

Accordingly, the Applicant respectfully requests the withdrawal of rejections for Claims 1-8, 10-15 and 21-36.

CONCLUSION

The Applicant believes the arguments set forth above traverse the Examiner's objections and rejections and therefore request these alleged grounds for objection and rejection be withdrawn. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect.

Dated: February 7, 2008

Peter Carroll, J.D., Ph.D.
Registration No. 32,837

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
617.984.0616

5 See, "Declaration Pursuant To 37 C.F.R. 1.132," paragraph 2.

6 Quinlan *et al.*, *Escherichia coli* as a platform for functional expression of plant P450 carotene hydroxylases, Archives of Biochemistry and Biophysics 458 (2007) 146–157.